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I, JANENE PEISKER, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2004900362 for a patent by UNITRACT SYRINGE PTY LTD as filed on 28 January 2004.

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PATENT OFFICE

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Eighth day of March 2005

J. K. + C

JANENE PEISKER
TEAM LEADER EXAMINATION
SUPPORT AND SALES

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AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: "RETRACTABLE SYRINGE AND PLUNGER THEREFOR"

The invention is described in the following statement:

TITLE

RETRACTABLE SYRINGE AND PLUNGER THEREFOR

FIELD OF THE INVENTION

THIS INVENTION relates to syringes and plungers therefor. More particularly, this invention relates to permanently retractable syringes where the syringe mechanism is automatically disabled.

BACKGROUND OF THE INVENTION

The problems of shared syringes are notorious. The practice of sharing syringes without adequate sterilisation between successive users is a major contributor to the transfer of Human Immunodeficiency Virus and Hepatitis with subsequent severe repercussions for the sufferer of such diseases and at a high cost to society of supporting and providing medical attention to those sufferers.

Another significant risk associated with unclean needles and syringes arises from the possibility of inadvertent needle-stick injuries. This is particularly a problem for law enforcement officers and paramedics who often encounter users of illegal drugs in their professional activities. Additionally, the habits of illegal drug users are such that dangerous by-products of their activities, such as discarded syringes, are often left in places of public access presenting a risk to the users of areas such as public parks and school grounds.

Used syringes are also dangerous in hospitals, medical centres and surgeries where needlestick injuries may injure doctors, nurses and other health professionals.

A recent development in syringes has been to design syringes where the needle is permanently retractable into the barrel of the syringe.

For example, International Publication WO 01/80930 describes a single-use retractable syringe that is highly effective in preventing syringe re-use by ensuring full depression of the plunger during fluid delivery and by ensuring permanent withdrawal of the needle by the plunger back into the syringe barrel.

In such cases, retraction is facilitated by a spring located on the plunger and external to the syringe barrel. Depression of the plunger during injection compresses the spring against the barrel collar and engages the retractable needle with the plunger end, release of the plunger at the end of injection forces the plunger and needle engaged therewith to retract into the barrel automatically.

OBJECT OF THE INVENTION

Although very effective, prior art retractable syringes having spring-driven retraction mechanisms have limitations.

One such limitation is that during delivery of the syringe contents, operating the plunger to compress a spring gives an undesirable feel to a user, which can provide a disincentive to use retractable syringes.

Another such limitation is that for higher volume syringes, such as 3, 5 and 10 mL syringes, the size of the spring needed to drive retraction of the plunger and needle can be inappropriate.

It is therefore an object of the invention to overcome or alleviate at least one of the deficiencies of the prior art, or at least provide a useful alternative.

SUMMARY OF THE INVENTION

The present invention is therefore broadly directed to a retractable syringe which comprises a mechanism to automatically disable the retractable syringe and

thereby prevent re-use of the retractable syringe, wherein the mechanism comprises a compressed spring retained in association with a plunger, decompression of which spring forces retraction of a plunger member having a retractable needle engaged therewith.

One preferred advantage of the syringe of the invention is that the spring is retained in a compressed state without the user having to compress the spring during plunger depression. This provides a smoother "feel" to the user during delivery.

A preferred feature of the automatic disabling mechanism is a ratchet and pawl system which prevents plunger withdrawal after depression of the plunger when delivering the contents of the syringe.

In a first aspect, the invention provides a plunger for a retractable syringe, said plunger comprising a first plunger member engageable with a second plunger member to co-operatively maintain a spring in an initial compressed state, said first plunger member capable of engaging a needle mount, in use disengagement of said first plunger member and said second plunger member facilitating decompression of said spring which forces retraction of said first plunger member and said needle mount.

In a second aspect, the invention provides a plunger for a retractable syringe, said plunger comprising a collar having at least one pawl for engaging said plunger, said plunger capable of engaging a needle mount and comprising at least one longitudinal ratchet engageable with said at least one pawl, in use operable to prevent withdrawal of said plunger during depression of said plunger.

In a third aspect, the invention provides a retractable syringe comprising the plunger of the first or second aspect.

In a preferred embodiment, said plunger comprises two opposed ratchets, each disposed longitudinally along said first plunger member.

According to this embodiment, said collar comprises two pawls, each said pawl engageable with a respective said opposed ratchet to prevent withdrawal of said plunger during or following depression of said plunger.

Each respective said ratchet may comprise a plurality of aligned steps, teeth, abutments or ridges oriented relative to said one or more pawls so as to be capable of engaging said one or more pawls, in use to prevent withdrawal of said plunger during depression of said plunger.

Suitably, in use said needle mount has a needle mounted thereto.

An advantage of the needle mount is that it enables mounting of any needle type, such as in the form of a luer fitting or regular needle fitting.

In a preferred embodiment, in use said first plunger member engages said needle mount at the end of plunger depression, decompression of said spring forcing retraction of said first plunger member, said needle mount and said retractable needle mounted thereto.

Even more preferably, said first plunger member comprises a locking means which co-operates with said collar to prevent subsequent depression of said plunger following retraction.

Throughout this specification, unless otherwise indicated, "comprise", "comprises" and "comprising" are used inclusively rather than exclusively, so that a

stated integer or group of integers may include one or more other non-stated integers or groups of integers.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting embodiments of the invention are described herein with reference to the accompanying drawings in which:

FIG. 1 is a perspective view of a longitudinal section through an embodiment of a retractable syringe;

FIG. 2 is a perspective view of an embodiment of a first plunger member;

FIG. 3 is another perspective view of an embodiment of a first plunger member;

FIG. 4 is another perspective view of an embodiment of a first plunger member and includes a sectional view of a ratchet;

FIG. 5 is a sectional view of a ratchet;

FIG. 6 is a perspective view of an embodiment of needle mount;

FIG.7 is a perspective view from plunger end of needle mount showing engagement with barrel clips;

FIG. 8 is a perspective view of the needle mount fitted to a syringe barrel;

FIG. 9 is a perspective view of an outer collar;

FIG. 10 is another perspective view of an outer collar;

FIG. 11 is a perspective view of an inner collar;

FIG. 12 is a plan view of a longitudinal section through an embodiment of a syringe during plunger withdrawal;

FIG. 13 is a plan view of a longitudinal section through an embodiment of a syringe during plunger depression;

FIG. 14 is an end view of needle end of barrel showing initial (A) and final (B) positions of plunger barbs and seal mount pins relative to barrel; and

FIG. 15 is a plan view showing spring decompression and needle retraction.

DETAILED DESCRIPTION OF THE INVENTION

Referring to an embodiment shown in FIG. 1, retractable syringe 10 comprises barrel 11, plunger 20 and retractable needle 12. Barrel 11 comprises needle end 13 to which is mounted retractable needle 12 via needle mount 40 and plunger end 14 at which are located finger grips 15A, 15B into which is mounted outer collar 50 having pawls 52A, 52B (pawl 52B not visible) barrel-engaging shoulders 55A, 55B (shoulder 55B not visible) that fit into respective locating slots 16A, 16B (slot 16B not visible) of plunger end 14 of barrel 11 of syringe 10.

Referring now to FIG 2, FIG. 3, FIG. 4 and FIG. 4, plunger 20 comprises first plunger member in the form of rod 21 and button 22 operable by a user, and second plunger member in the form of seal mount 23. Seal 90 is mounted to plunger 20 by way of seal mount 23 to prevent leakage of fluid from barrel 11. An additional O-ring (not shown) may also be present to seal between rod 21 and seal mount 23. Seal mount also includes tapered pins 28A, 28B for engaging slots (not shown) inside needle end of 13 barrel 11, as will be described in more detail hereinafter

Plunger rod 21 comprises a pair of opposed ratchets 24, a locking means 35 in the form of plunger pawls 25A, 25B, reduced diameter portion 26 over which spring 70 is loaded, and rim 27 which cooperates with seal mount 23 to maintain spring 70

in a compressed state until retraction of needle mount 40 and needle 12 is required.

Referring in particular to FIG. 2, plunger rod 21 also includes opposed, substantially parallel retraction slots 34 which are connected to ratchets 24 by deviations 39 respectively. Each retraction slot terminates at ledge 91.

Referring particularly to FIG. 4, plunger rod 21 further comprises means 36 for engaging needle mount 40. In this embodiment, means 36 comprises opposed barbs 37A, 37B having barb ends 38A, 38B that are oriented appropriately to engage needle mount 40 at the end of plunger 20 depression, as will be described in more detail hereinafter with reference to FIG. 14.

Coupling between rod 21 and seal mount 23 is achieved in this embodiment by a bayonet coupling, the rod component 35 of which coupling is shown in FIG.4. However, any releasable coupling may be used as an alternative, as long as release may be achieved with minimal rotation between inner rod 21 and seal mount 23.

Referring to FIG. 5, ratchets 24 each comprise a plurality of steps 30 which each have deep shoulder 31 and shallow shoulder 32. There is also an inclined surface 33 intermediate adjacent steps 30.

Referring now to FIG. 6, FIG. 7 and FIG. 8, needle mount 40 comprises body 41 having central bore 42 and barb recesses 43 having angled ledges 44, lip 45 and upper rim 48. Needle mount body 41 further comprises opposed, tapered recesses 46 that engage respective tabs (not shown) on inside wall of barrel 11 to thereby fix needle mount 40 in position and limit movement of needle mount 40 toward needle end 13 of barrel 11.

Referring particularly to FIG.6 and FIG. 7, barrel 11 comprises respective barrel clips 18, each comprising clip end 19 that clips under respective upper rims 48 of recesses 43. Disengagement of barrel clips 18 from needle mount 40 to allow retraction of needle mount 40 will be described hereinafter.

Referring particularly to FIG. 8, a tight seal is formed between needle mount 40 and barrel 11 by O-ring 80.

A feature of needle mount 40 is that it may include whichever type of needle fitting is desired, such as luer 47, although without limitation thereto.

An advantage provided by needle mount 40 is that a user may replace the needle should it become bent or burred, or should the needle gauge be changed *(i.e* between filling and delivery) without affecting the retraction mechanism.

Referring now to FIG 9, outer collar 50 comprises outer collar body 51 having pawls 52A, 52B, channels 53A, 53B, fingers 54A, 54B and barrel-engaging shoulders 55A, 55B. Pawls 52A, 52B are resiliently deformable from an initial position where engagement with steps 30 is prevented to a position where pawls 52A, 52B can engage respective steps 30 to prevent plunger withdrawal, as will be described in more detail hereinafter.

Another view of outer collar 50 is provided in FIG. 10, showing recesses 56A, 56B having stops 57A, 57B and keyways 58A, 58B.

As can be seen in FIG 11, inner collar 60 comprises inner collar body 61 having first projection 62A and second projection 62B, which projections are resiliently deformable. Inner collar body 61 also comprises tabs 64A, 64B.

With this in mind and with reference to FIG. 12 and FIG. 13, when assembled, barrel-engaging shoulders 55A, 55B of outer collar 50 fit into respective locating slots 16A, 16B of plunger end 14 of barrel 11 of syringe 10. Tabs 64A, 64B of inner collar 60 are slidably located in channels 53A, 53B of outer collar 50. This aligns inner collar 60 and outer collar 50, preventing rotation therebetween.

In this correctly aligned configuration, first projection 62A and second projection 62B of inner collar 60 are initially, respectively positioned between pawls 52A, 52B of outer collar 50 and ratchets 24A, 24B, thereby preventing pawls 52A, 52B of outer collar 50 contacting steps 30A, 30B.

Initially, plunger barbs 37 are offset (*i.e* non-aligned) relative to barb recesses 43 in needle mount 40 so that, initially, they do not engage barb recesses 43 in needle mount 40, thereby ensuring that needle mount 40 and needle 12 are not inadvertently retracted when filling syringe 10.

It can be seen that during withdrawal of plunger 20 to fill barrel 11, pawls 52A, 52B tend to exert an inward pressure on projections 62A, 62B thereby clamping projections 62A, 62B in position. Accordingly, projections 62A, 62B pass over respective steps 30A, 30B with minimal interference thereby providing a "smooth" feel during plunger 20 withdrawal.

Upon depression of plunger 20, projections 62A, 62B of inner collar respectively engage shallow shoulders 32A, 32B of steps 30A, 30B at whichever point has been reached during withdrawal of plunger 20. The force applied to plunger 20 by the user pushes shallow shoulders 32A, 32B of steps 30A, 30B against projections 62A, 62B respectively, thereby forcing inner collar 60 out of its initial

position engaged with outer collar 50 to thereby expose pawls 52A, 52B. It can be seen in FIG. 13 that projections 62A, 62B return to a non-deformed position and no longer contact ratchets 24A, 24B.

Referring again to FIG. 13, due to the respective orientations of pawls 52A, 52B of outer collar 50, the direction of inclined surfaces 33A, 33B and the relative shallowness of shallow shoulders 32A, 32B, pawls 52A, 52B do not appreciably interfere with depression of plunger 20 which provides a "smooth" feel to the user during delivery. However, should the user attempt to subsequently withdraw plunger 20 to re-fill syringe 10, pawls 52A, 52B respectively engage deep shoulders 31A, 31B of steps 30A, 30B in ratchets 24A, 24B to thereby prevent withdrawal of plunger 20 and re-use of syringe 10.

At the end of delivery, plunger 20 reaches needle end 13 of barrel 11. At this point, pawls 52A, 52B of outer collar 50 slidably move into respective retraction slots 34A, 34B, which drives slight rotation of plunger 20 relative to barrel.

As evident by from comparing FIG. 14 A with FIG. 14B, this rotation aligns barbs 37A, 33B on inner plunger rod 21 with retraction recesses 43A, 43B on needle mount 40 and also aligns tapered pins 28A, 28B of seal mount 23 with respective slots 95A, 95B inside needle end of 13 barrel 11, although the relative positions of aligns barbs 37 with respect to tapered pins 28A, 28B of seal mount 23 need not be exactly as shown in FIG. 14.

Seal mount 23 and inner plunger rod 21 are then disengaged following further depression of plunger 20 causing barbs 37 of inner plunger rod 21 to engage barb

recesses 43 in needle mount 40 and causing tapered pins 28A, 28B to engage slots 95A, 95B of barrel 11.

With regard to engagement between plunger rod 21 and needle mount 40, lip 45 of each barb recess 43 assists barb ends 38A, 38B engaging needle mount 40. Angled ledges 44 of each barb recess 43 are slightly offset with respect to corresponding barbs 37 which drives slight rotation of plunger rod 21 relative to seal mount 23.

With regard to engagement between seal mount 23 and barrel 11, the taper of pins 28A, 28B and slots 95A, 95B allows some counter-rotation of seal mount 23 relative to plunger rod 21 which further assists uncoupling of bayonet coupling 35 between plunger rod 21 and seal mount 23 to thereby release plunger rod 21 from seal mount 23.

As shown in FIG. 15, disengagement of plunger rod 21 and seal mount 23 allows decompression of spring 70 which pushes against seal mount 23 and rim 27 on inner plunger rod 21 (in the direction indicated by the solid arrow) to thereby force retraction of inner plunger rod 21 together with needle mount 40 and needle 12 engaged therewith. Seal 23 remains at needle end 13 of barrel 11.

With particular reference also to FIG. 6 and FIG. 7, in order to release needle mount 40 from barrel 11, barbs 37A, 37B of plunger rod 21 as well as engaging needle mount recesses 43A, 43B forcibly displace respective barrel clips 18 laterally from engagement with upper rim 48 of recess 43 and thereby allow needle mount 40 to be retracted when engaged with inner plunger member 21.

Reference to FIG. 4 and FIG. 10 in particular, will assist in understanding an embodiment of the final lockout mechanism.

Disengagement of plunger rod 21 from seal mount 23 allows decompression of spring 70 and retraction of plunger rod 21 with needle mount 40 and needle 12 attached thereto. When plunger rod 21 retracts, pawls 52A, 52B of outer collar 50 have slidably moved from respective ratchets 24A, 24B via respective deviations 39 into retraction slots 34. Retraction slots 34 are configured to allow unimpeded slidable movement of outer collar pawls 52A, 52B therein until pawls 52A, 52B bear against ledges 91 of retraction slots 34 at which point plunger rod 21 cannot be retracted any further (*e.g.* to prevent complete withdrawal of plunger rod 21 from barrel 11).

During retraction of plunger rod 21, plunger pawls 25A, 25B pass out through outer collar 50 via respective keyways 58A, 58B in outer collar 50, but once this has occurred, subsequent depression of plunger rod 21 is prevented by plunger pawls 25A, 25B respectively engaging steps 57A, 57B in recesses 56A, 56B in outer collar 50.

It will be understood in light if the foregoing that the invention provides a robust, simple to operate automatically-disabling syringe that prevents subsequent reuse and thereby minimizes the potential for disease transfer while also reducing the likelihood of needlestick injuries to the user.

Throughout the specification, the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Various changes and modifications may be made to

the embodiments described and illustrated without departing from the present invention.

DATED this twenty-eighth day of January 2004

UNITRACT SYRINGE PTY LTD

by its Patent Attorneys

FISHER ADAMS KELLY

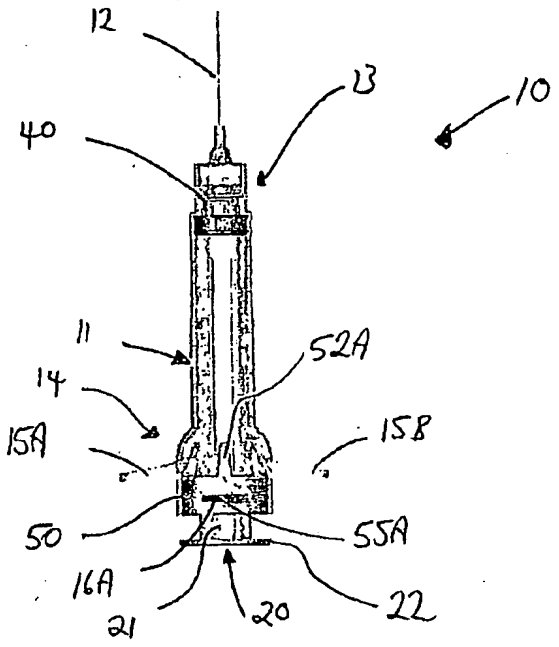


FIG. 1

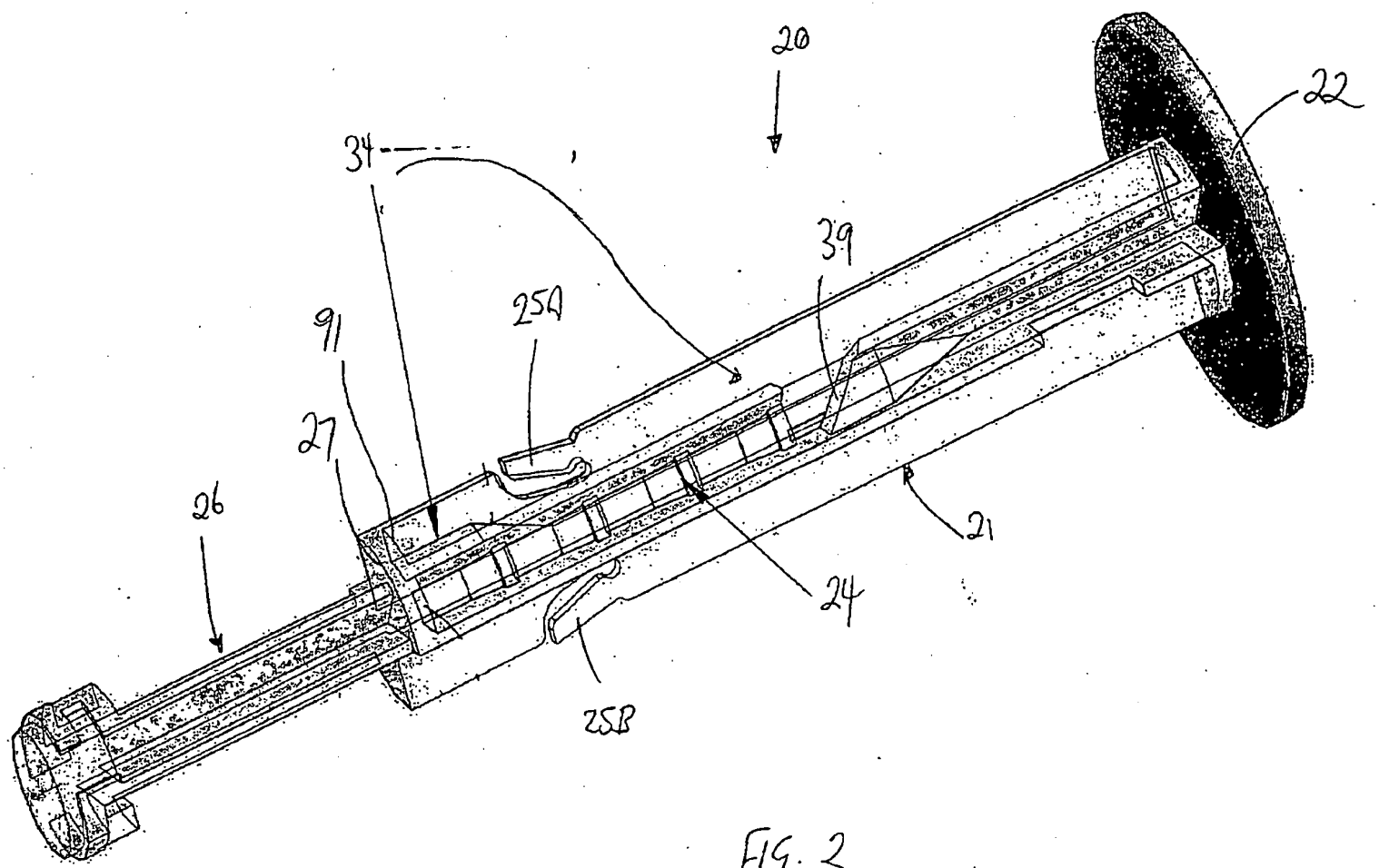


FIG. 2

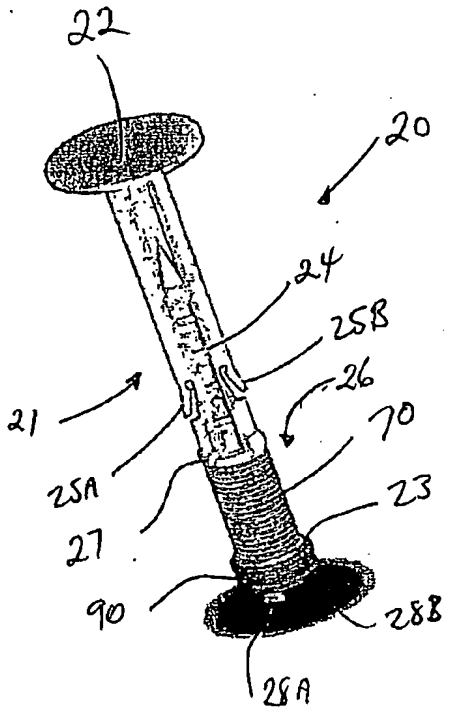


FIG. 3

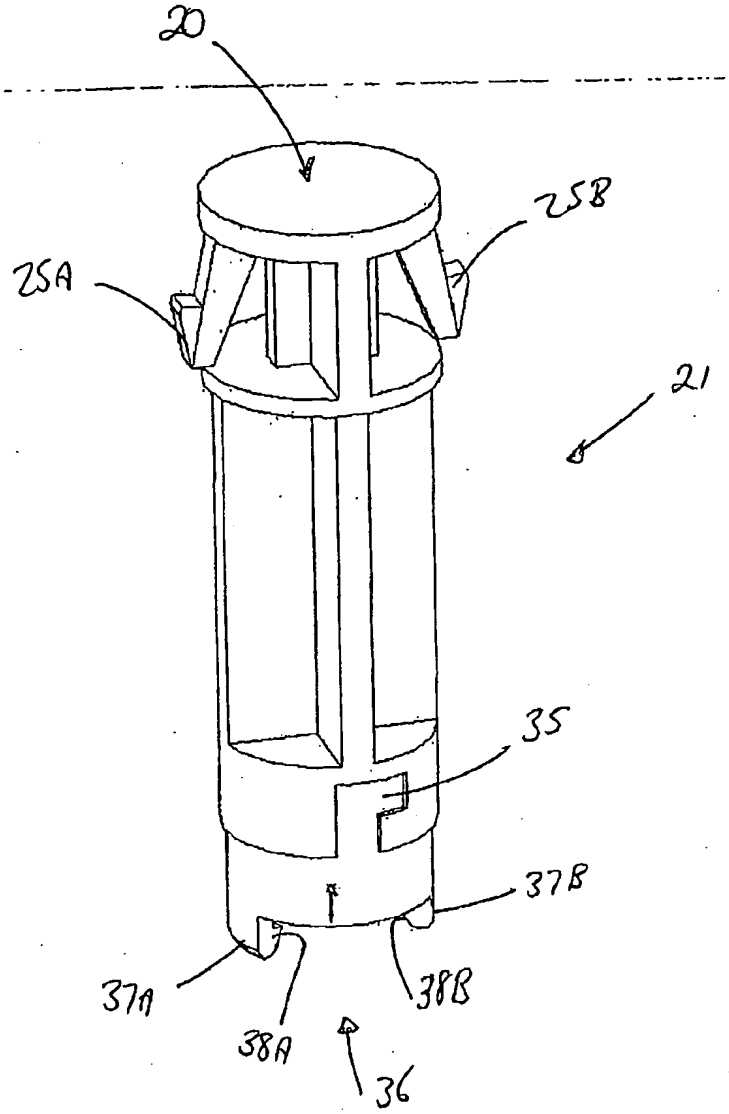


FIG. 4

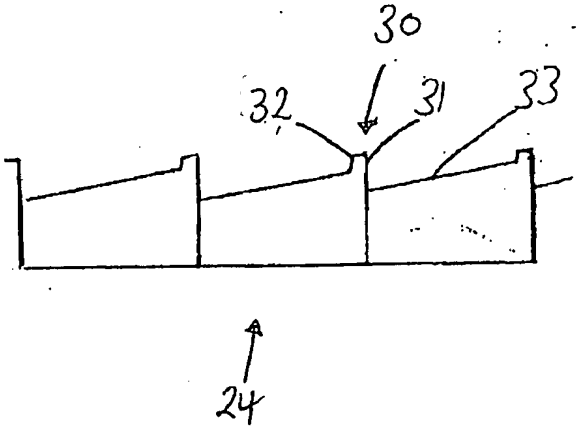


FIG 5

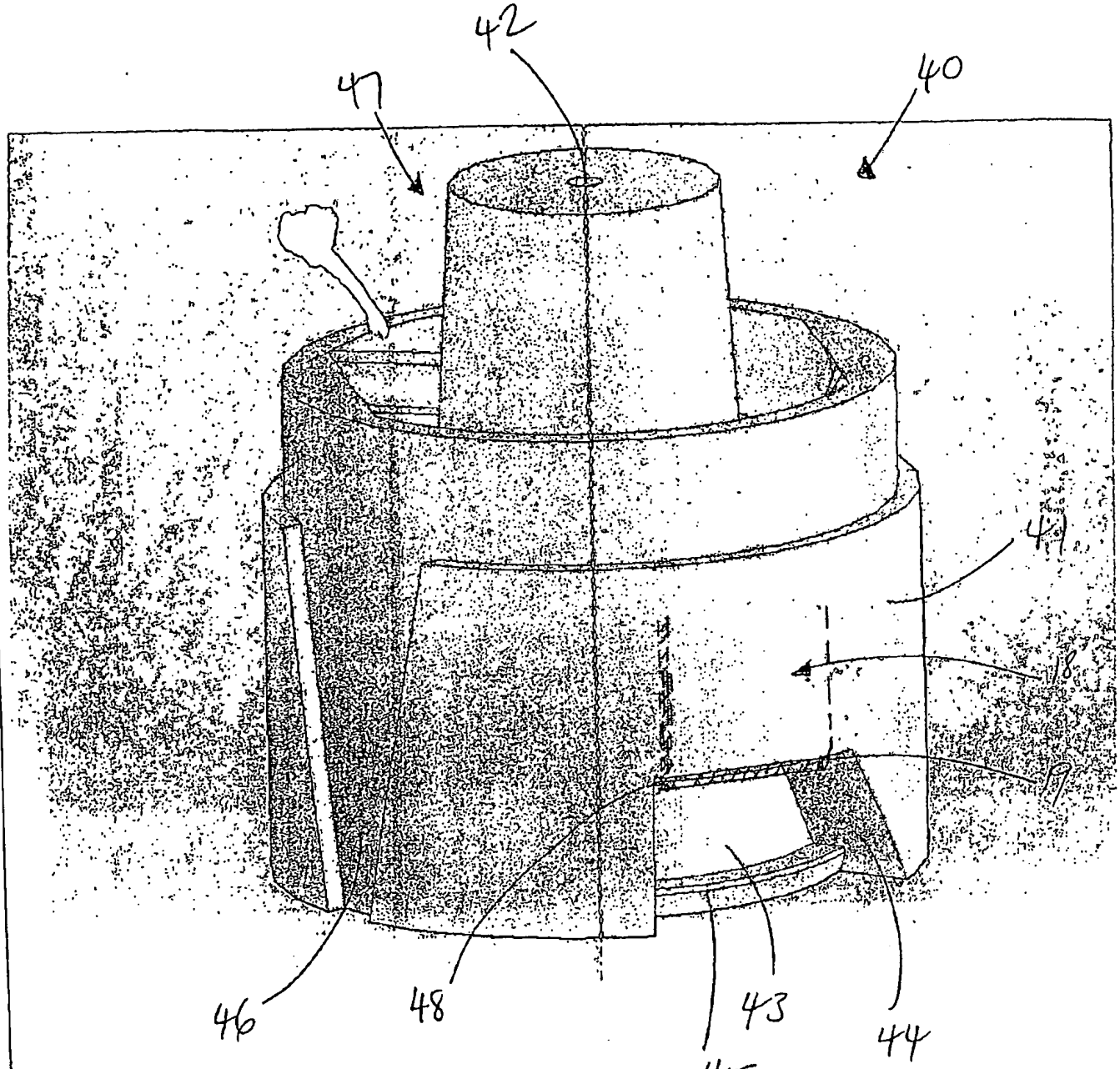


FIG. 6

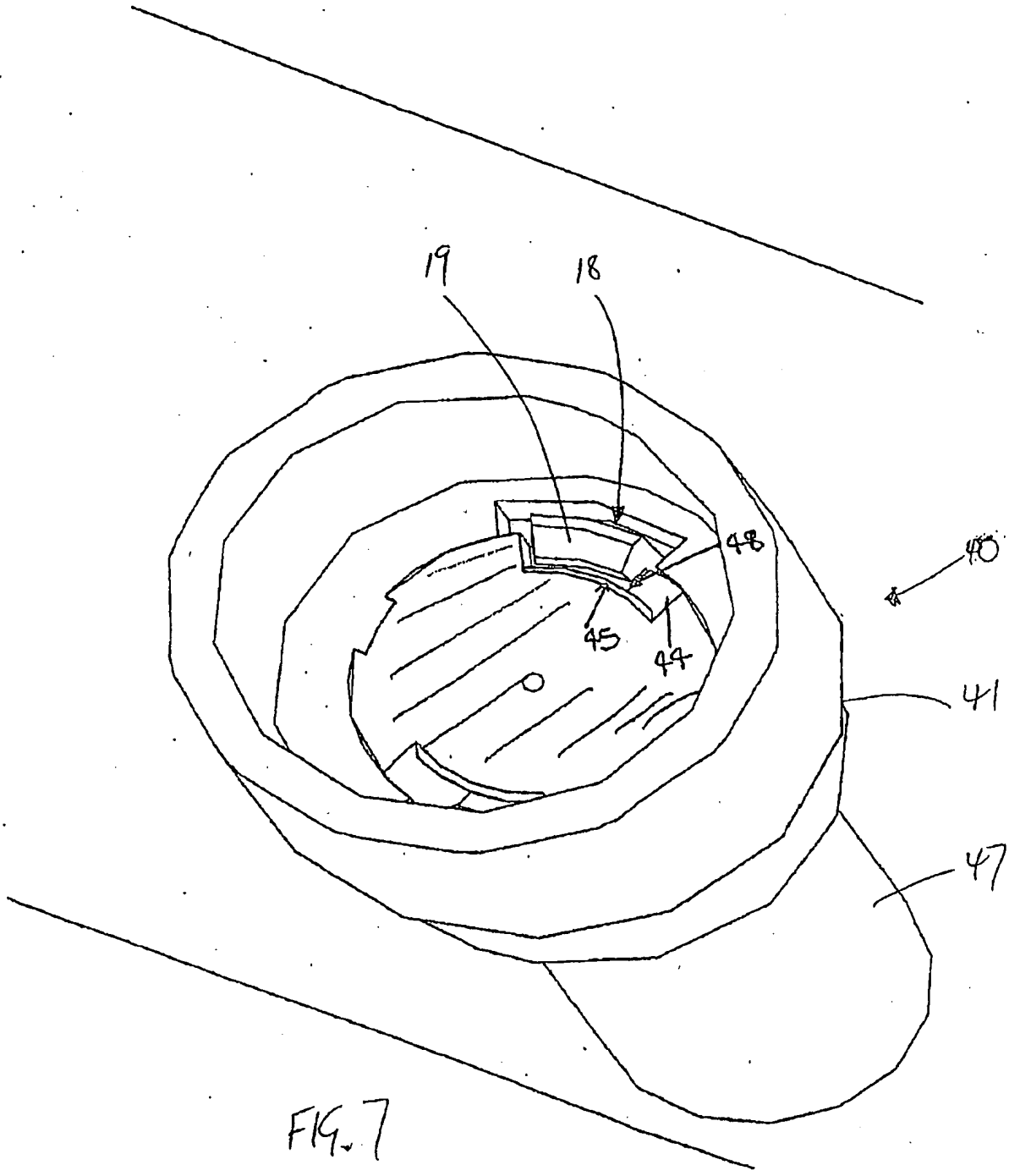


FIG. 7

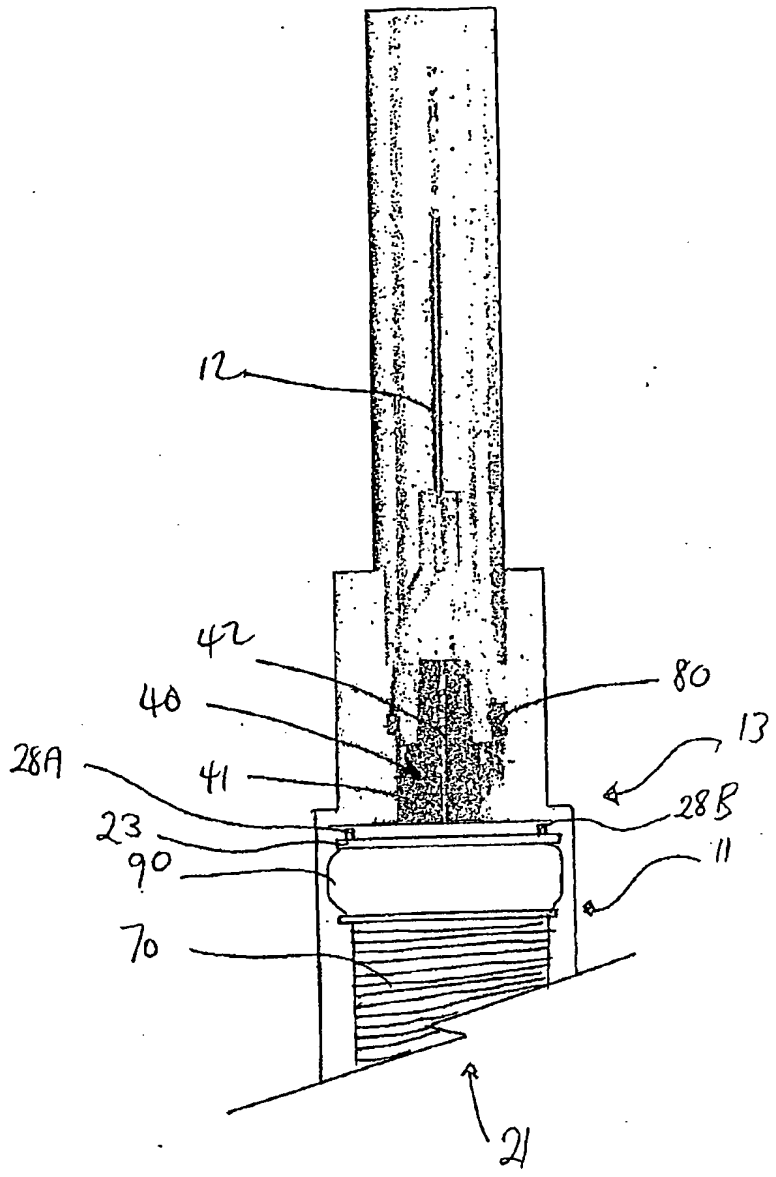


FIG 8

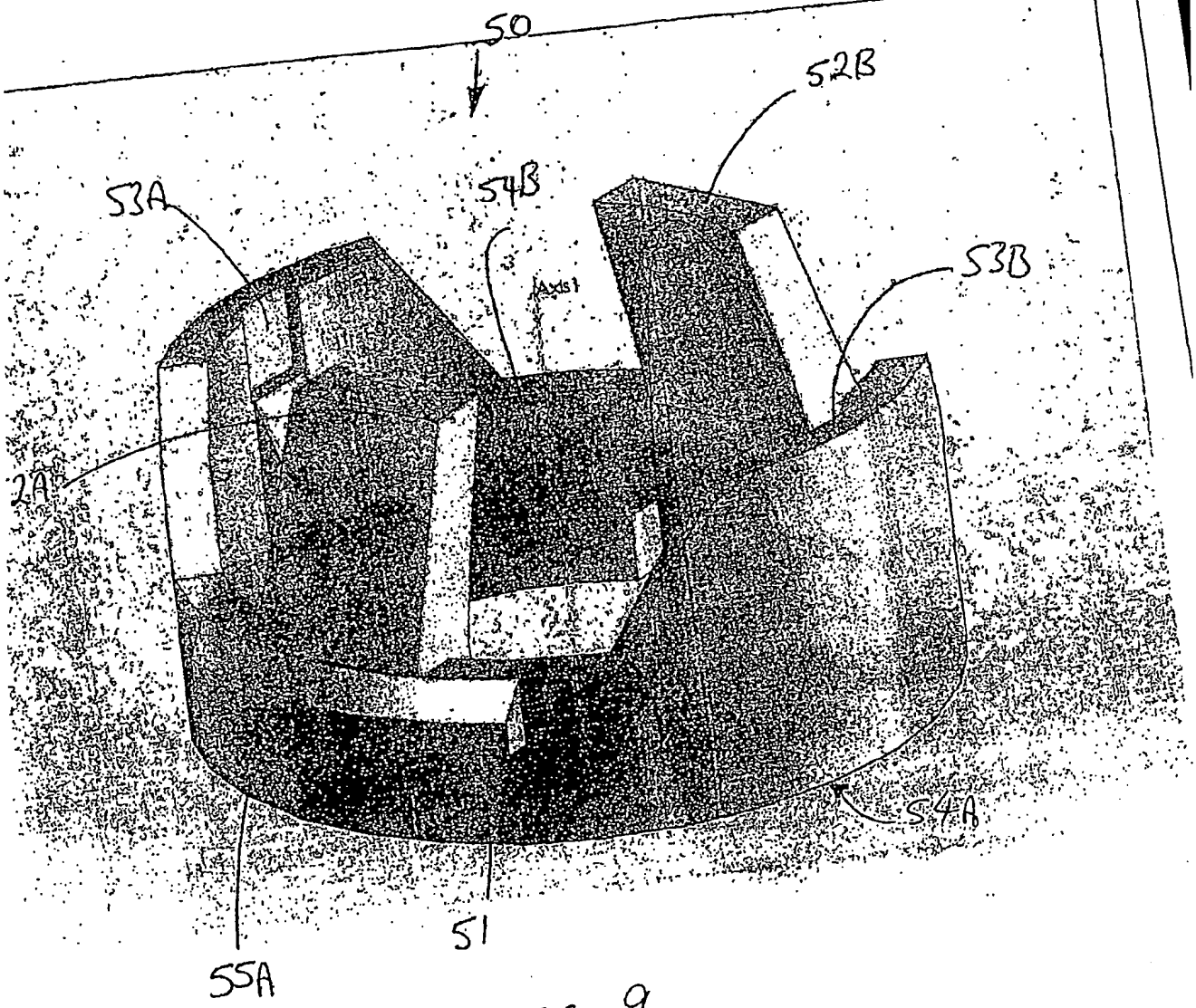


FIG. 9

Fig. 10

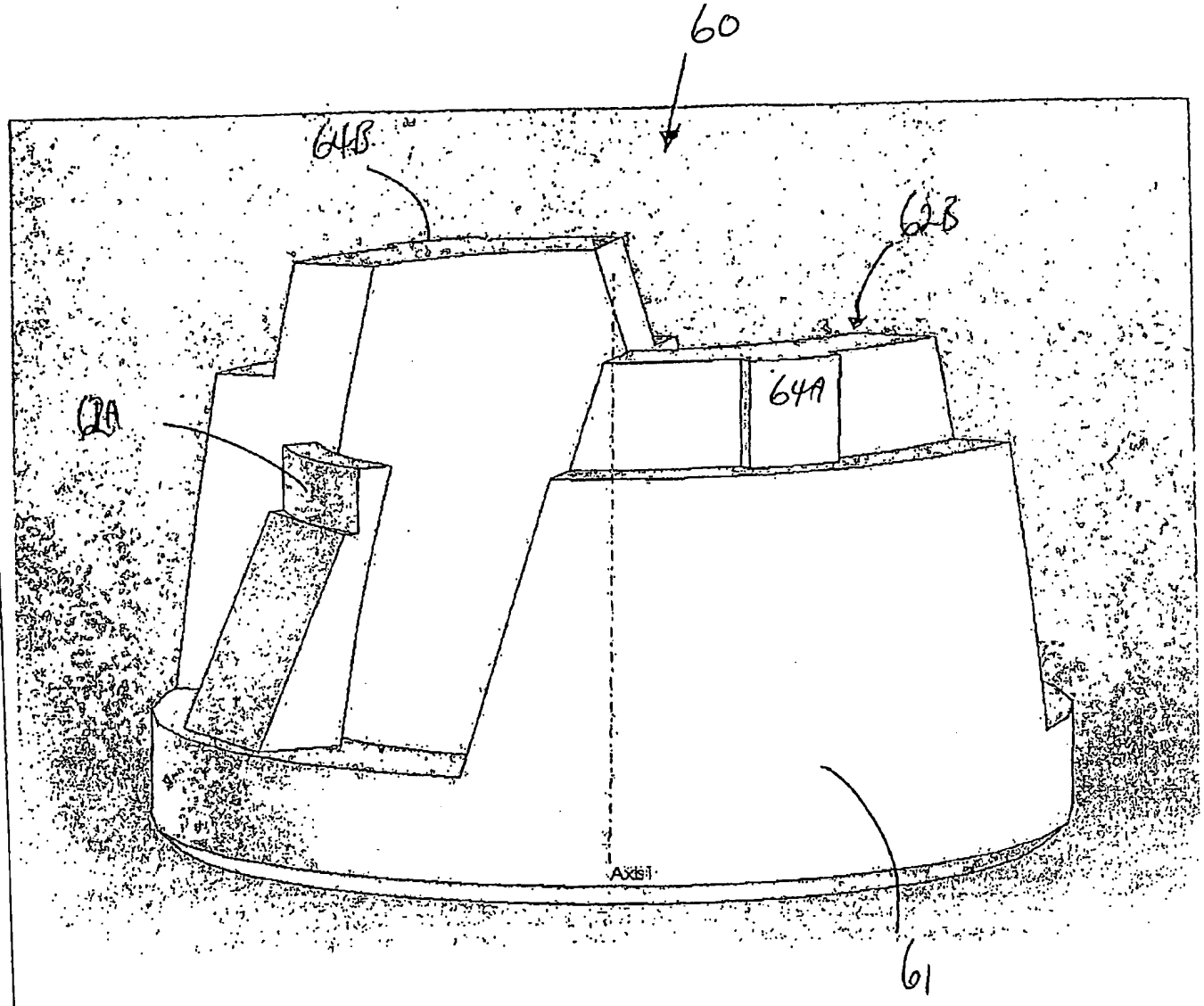


FIG. 11

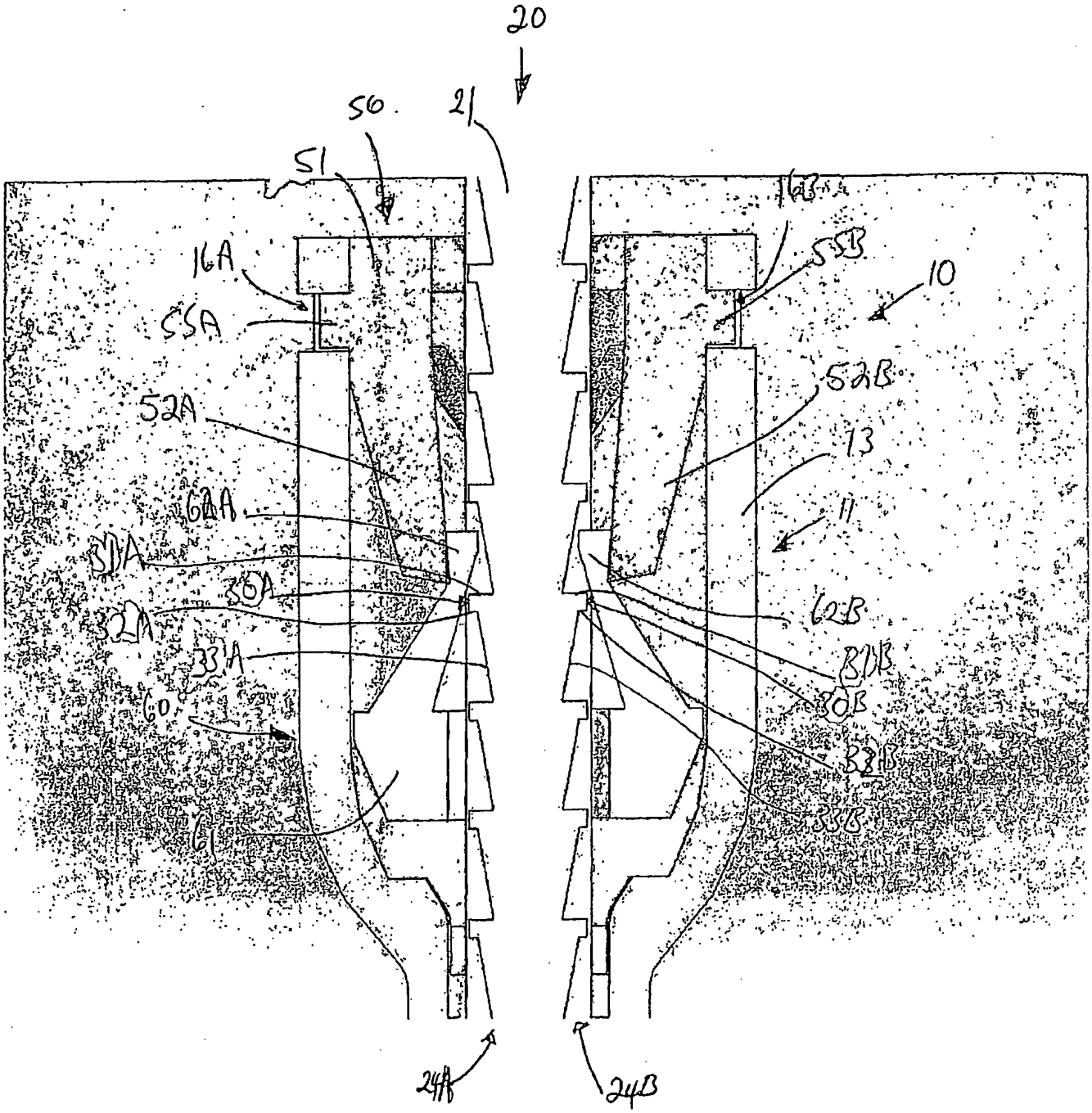
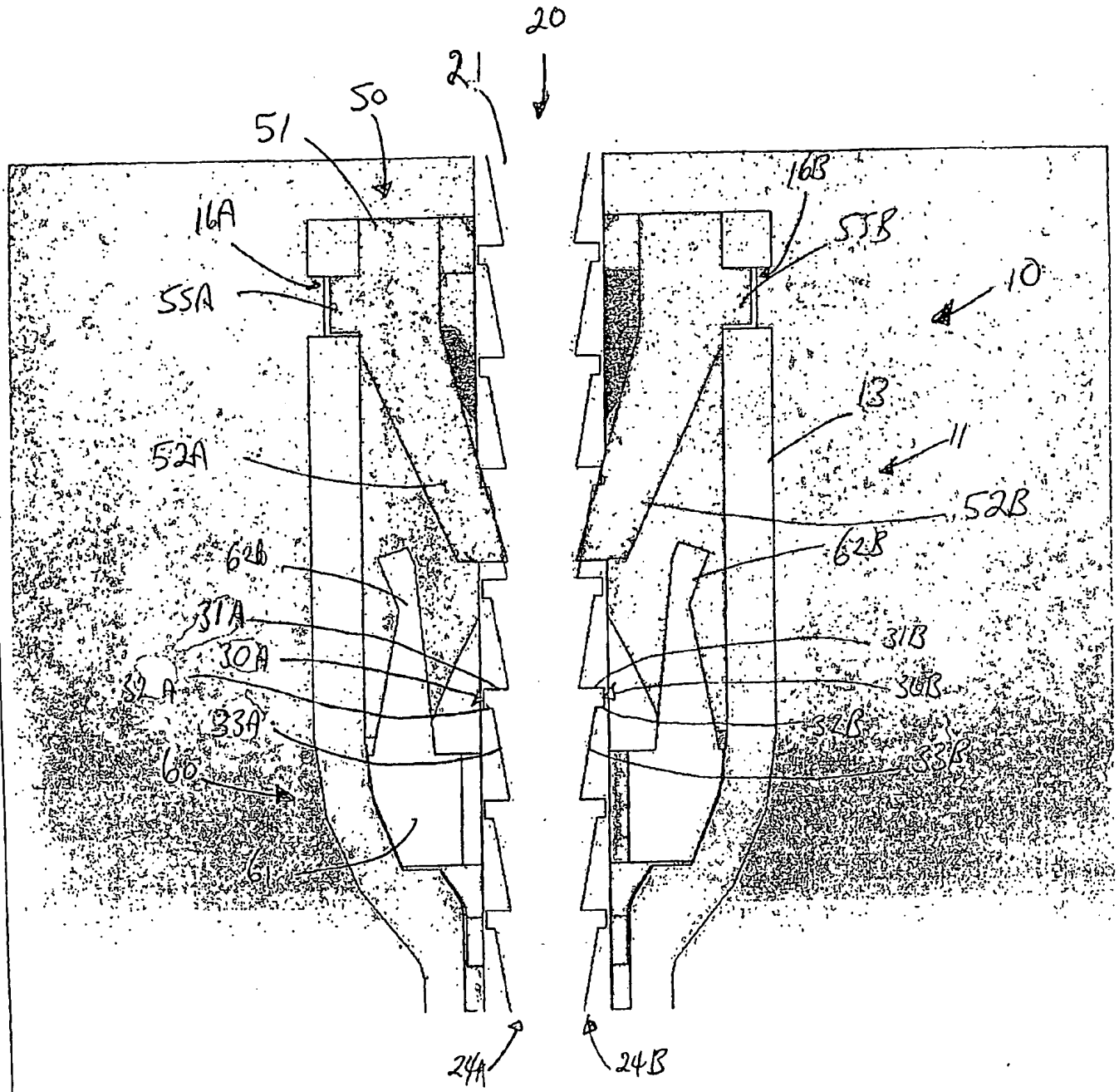

20
21
50
51
16A
55A
52A
62A
53A
30A
32A
33A
60
61
24A
16B
55B
10
52B
13
11
62B
53B
30B
32B
33B
24B

FIG 12


20
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62B
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30B
32B
33B
24B

FIG 13

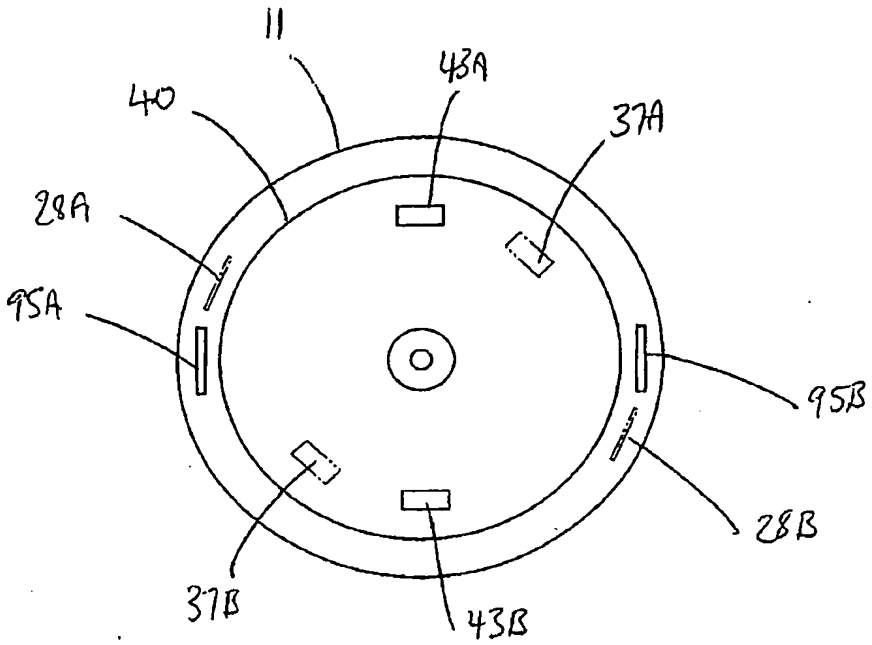

Fig.14a

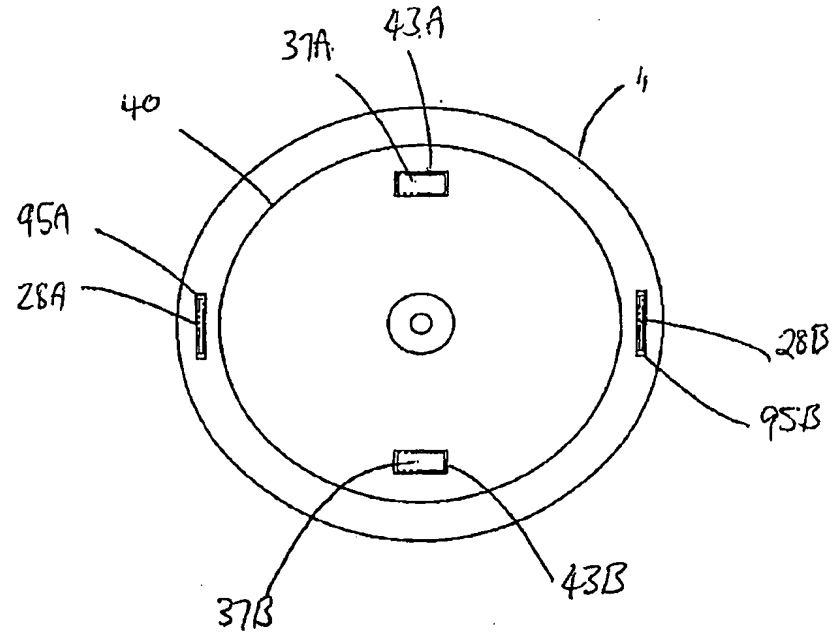

Fig.14b

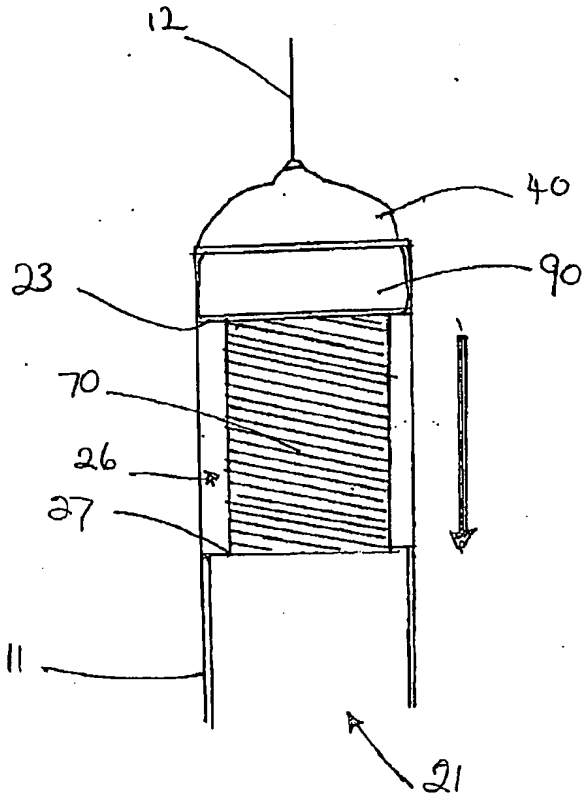

FIG. 15

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World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

PCT/AU2005/000107

Australian Government

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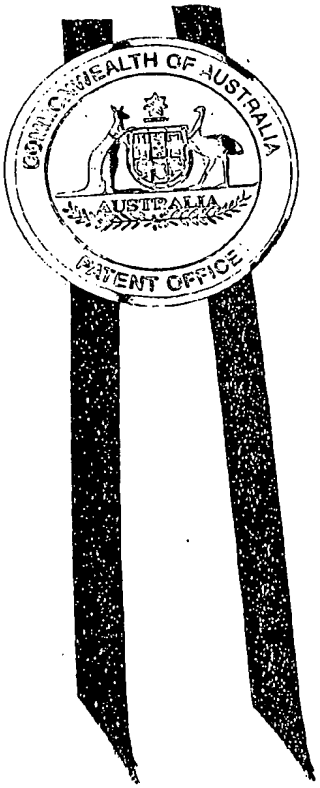
I, JANENE PEISKER, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2004906116 for a patent by UNITRACT SYRINGE PTY LTD as filed on 22 October 2004.



WITNESS my hand this
Eighth day of March 2005

JANENE PEISKER
TEAM LEADER EXAMINATION
SUPPORT AND SALES

P/00/009
Regulation 3.2

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: "RETRACTABLE SYRINGE WITH PLUNGER DISABLING SYSTEM"

The Invention is described in the following statement:

TITLE

RETRACTABLE SYRINGE WITH PLUNGER DISABLING SYSTEM

FIELD OF THE INVENTION

THIS INVENTION relates to syringes and plungers therefor. More particularly, this invention relates to permanently retractable syringes where the plunger can be automatically disabled.

BACKGROUND OF THE INVENTION

The practice of sharing syringes without adequate sterilisation between successive users is a major contributor to the transfer of Human Immunodeficiency Virus and Hepatitis with subsequent severe repercussions for the sufferer of such diseases and at a high cost to society of supporting and providing medical attention to those sufferers.

Another significant risk associated with unclean needles and syringes arises from the possibility of inadvertent needle-stick injuries. This is particularly a problem for law enforcement officers and paramedics who often encounter users of illegal drugs in their professional activities. Additionally, the habits of illegal drug users are such that dangerous by-products of their activities, such as discarded syringes, are often left in places of public access presenting a risk to the users of areas such as public parks and school grounds.

Used syringes are also dangerous in hospitals, medical centres and surgeries where needlestick injuries may injure doctors, nurses and other health professionals.

A recent development in syringes has been to design syringes where the needle is permanently retractable into the barrel of the syringe.

For example, International Publication WO 01/80930 describes a single-use retractable syringe that is highly effective in preventing syringe re-use by ensuring full depression of the plunger during fluid delivery and by ensuring permanent withdrawal of the needle by the plunger back into the syringe barrel.

In such cases, retraction is facilitated by a spring located on the plunger and external to the syringe barrel. Depression of the plunger during injection compresses the spring against the barrel collar and engages the retractable needle with the plunger end, release of the plunger at the end of injection forces the plunger and needle engaged therewith to retract into the barrel automatically.

OBJECT OF THE INVENTION

Although very effective, prior art retractable syringes having spring-driven retraction mechanisms have limitations.

One such limitation is that during delivery of the syringe contents, operating the plunger to compress a spring gives an undesirable feel to a user, which can provide a disincentive to use retractable syringes.

Another such limitation is that for higher volume syringes, such as 3, 5 and 10 mL syringes, the size of the spring needed to drive retraction of the plunger and needle can be too large to fit into the syringe.

It is therefore an object of the invention to overcome or alleviate at least one of the deficiencies of the prior art, or at least provide a useful alternative.

SUMMARY OF THE INVENTION

The present invention is therefore broadly directed to a retractable syringe which comprises a mechanism to automatically disable the retractable syringe and

thereby prevent re-use of the retractable syringe, wherein the mechanism comprises a compressed spring retained in association with a plunger, decompression of which spring forces retraction of a plunger member having a retractable needle engaged therewith.

A preferred advantage of the syringe of the invention is that the spring is retained in a compressed state without the user having to compress the spring during plunger depression. This provides a smoother "feel" to the user during delivery.

In a first aspect, the invention provides a plunger for a retractable syringe, said plunger comprising a first plunger member engageable with a second plunger member to co-operatively maintain a spring in an initial compressed state, said first plunger member capable of engaging a needle mount, in use disengagement of said first plunger member and said second plunger member facilitating decompression of said spring which forces retraction of said first plunger member and said needle mount.

In a second aspect, the invention provides a retractable syringe comprising the plunger of the first aspect.

In a third aspect, the invention provides a retractable syringe comprising the retractable syringe of the second aspect and a needle mounted to said needle mount.

In a preferred embodiment, said first plunger member is engageable with said needle mount at the end of plunger depression, whereby decompression of said spring forces retraction of said first plunger member, said needle mount and said retractable needle when mounted thereto.

Preferably, said syringe further comprises a collar that includes one or more projections engageable with said plunger.

In a preferred form, said one or more projections of said collar and said first plunger member are co-operable to form a plunger disabling means that is capable of preventing subsequent depression and/or withdrawal of said first plunger member following retraction of the needle mount and needle.

In another preferred from, said syringe is arranged so that following retraction of the needle mount and needle, subsequent coupling of a needle mount and/or needle to the syringe is disabled to thereby prevent syringe re-use.

Throughout this specification, unless otherwise indicated, "comprise", "comprises" and "comprising" are used inclusively rather than exclusively, so that a stated integer or group of integers may include one or more other non-stated integers or groups of integers.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting embodiments of the invention are described herein with reference to the accompanying drawings in which:

FIG. 1 is a side view of an embodiment of a retractable syringe;

FIG. 2 is a perspective view of an embodiment of a first plunger member, a second plunger member with a seal and a spring with inset showing coupling means of first plunger member and second plunger member;

FIG. 3 is a perspective view of an embodiment of a barrel;

FIG. 4 is a perspective view of an embodiment of a barrel insert, an O-ring and a needle mount;

FIG. 5 is a perspective view of an embodiment of a collar;

FIG. 6 is a perspective view showing (A) the interaction of a collar projection and a slot in a first plunger member during plunger withdrawal; and (B) movement of the projection from the slot following plunger depression;

FIG. 7A and 7B are sequential perspective views showing engagement between a plunger rod and a needle mount;

FIG. 8 is a sectional view of a first plunger member just prior to disengaging a barrel insert from a needle mount;

FIG. 9 is a sectional view of a first plunger member having disengaged a barrel insert from a needle mount; and

FIG. 10 is a perspective view of an embodiment of a syringe disabling means.

DETAILED DESCRIPTION OF THE INVENTION

Referring to an embodiment shown in FIG. 1, retractable syringe 10 comprises barrel 20, plunger 30 and needle mount 40 with retractable needle 12. Needle mount 40 is mounted at needle end 23 of barrel 20 with barrel insert 50 and O-ring 55. Finger grips 25A, 25B are provided at plunger end 24 of barrel 20, at which end is mounted collar 60. Plunger 30 comprises first plunger member 31 with button 32 operable by a user and second plunger member 33 and seal 34 mounted thereto, coupled to first plunger member 31 to co-operatively maintain spring 70 in a compressed state until retraction of needle mount 40 and needle 12.

Referring now to FIG 2, plunger 30 comprises first plunger member in the form of plunger rod 31 having button 32 operable by a user, and second plunger member in the form of seal mount 33. When assembled, seal 34 is mounted to seat 35

in seal mount 33, which in use, prevents or minimizes leakage of fluid between plunger 30 and internal wall 21 of barrel 20.

As specifically shown in the inset to FIG. 2, seal mount 33 is mounted to plunger rod 31 by a coupling means 300, which in this embodiment is a bayonet coupling formed between tabs 37A, 37B in seal mount 33 and respective coupling indents 38A, 38B in plunger rod 31. Coupling indents 38A, 38B are configured to allow restricted longitudinal movement (no more than about 1-2 mm) of seal mount 33 relative to plunger rod 31 when mounted thereto.

Plunger rod 31 has a plurality of elongate, parallel vanes 310A, 310B, 310C, 310D and 310E extending longitudinally along plunger rod 31. Vanes 310A, 310B define slot 311 having gate 312. Vanes 310B and 310C define retraction space 313.

Plunger rod 31 has reduced diameter portion 320 over which spring 70 is loaded, spring 70 bearing against rims 330A, 330B which thus cooperate with seal mount 33 when coupled to plunger rod 31 to maintain spring 70 in a compressed state until retraction of needle mount 40 and needle 12 is required. Spring 70 is shown non-compressed in FIG. 2.

Plunger rod 31 further comprises means 340 for engaging needle mount 40. In this embodiment, means 340 comprises opposed barbed arms 341A, 341B having barb ends 342A, 342B that can engage needle mount 40 at the end of plunger 30 depression, as will be described in more detail hereinafter.

Plunger rod further comprises steps 350A, 350B (not shown) which, together with ledges 351A, 351B, form part of disabling means 80 to be described in more detail hereinafter.

Referring to FIG. 3, barrel 20 is adapted so that needle mount 40 and barrel insert 50 can be fitted at needle end 23, while collar 60 can be mounted at plunger end 24. Tapered tabs 28A, 28B (not shown) facilitate mounting and retention of needle mount 40. Barrel 20 also comprises locating slots 29A, 29B at plunger end 24 that facilitate mounting and retention of collar 60 and, at needle end 23, seat 210 for mounting O-ring 55.

With reference to FIG. 3 and FIG. 4, barrel insert 50 has annular body 51 with base 52 and arms 53A, 53B having respective grips 56A, 56B with angled faces 57A, 57B. O-ring 55 is fitted into seat 210 of barrel 20 to effect a seal between needle mount body 41 and internal wall 21 of barrel 20.

Needle mount 40 comprises body 41 having central bore 42, base rim 43 and plunger-engaging portions 44A, 44B (not visible in FIG. 4) that comprise respective barb recesses 45A, 45B, angled faces 46A, 46B, lips 47A, 47B and upper ledges 48A, 48B. Needle mount body 41 further comprises opposed, tapered recesses 49A, 49B that in use are engaged by respective, tapered tabs 28A, 28B on inside wall 21 of barrel 20 to thereby fix needle mount 40 in position at needle end 23 of barrel 20 and limit movement of needle mount 40 toward needle end 23.

When assembled into syringe 10, base rim 43 of needle mount 40 is held by grips 56A, 56B of respective arms 53A, 53B of barrel insert 50, which prevents unwanted movement of needle mount 40 in the direction of plunger end 24 of barrel 20. Preferably, arms 53A, 53B of barrel insert 50 are oriented at approximately 90° relative to respective plunger-engaging portions 44A, 44B of needle mount 40.

Arms 53A, 53B are resiliently deformable in the direction indicated by solid arrows. Radial outward movement of arms 53A, 53B allows release of needle mount 40 for subsequent retraction of needle mount 40 as will be described in more detail hereinafter.

An advantage provided by needle mount 40 is that a user may replace the needle should it become bent or burred, or should the needle gauge be changed *(i.e* between filling and delivery) without affecting the retraction mechanism.

A feature of needle mount 40 is that it may include whichever type of needle fitting is desired, such as luer taper 400, although without limitation thereto.

Referring to FIG. 3 and FIG. 5, barrel 20 comprises locating slots 29A, 29B (slot 29A not visible) in plunger end 24, which facilitate mounting of collar 60. Collar 60 has body 61 with a plurality of projections in the form of pawls 62A, 62B and ribs 63A, 63B and barrel-engaging shoulders 65A, 65B (shoulder 65B not visible) that fit into respective locating slots 29A, 29B (not shown) of barrel 20 to thereby mount collar 60 into plunger end 24 of barrel 20.

The operation of an assembled syringe 10 will now be described.

As shown in FIG. 2, plunger 30 is assembled so that first plunger member 31 and second plunger member 33 are coupled by way of coupling means 300 to thereby maintain spring 70 in a compressed state until retraction of needle mount 40 and needle 12 fitted thereto, is required.

Referring to FIG. 6A, during withdrawal of plunger 30 to fill barrel 20 with fluid, rib 63A of collar 60 is slidably located in slot 311 of plunger rod 31 and rib 63B of collar bears against vane 310D (not visible in FIG. 6). This arrangement

prevents rotation of plunger relative to collar 60 and needle mount 40 and maintains alignment of plunger means 340 for engaging needle mount 40 and plunger-engaging portions 44A, 44B of needle mount 40, at approximately 90° relative to respective arms 53A, 53B of barrel insert 50.

Withdrawal of plunger 30 is limited by abutment 360 in slot 311 bearing against rib 63A of collar 60. The particular position of abutment 360 in slot 311 will therefore determine the length of travel of plunger 30 and hence the volume of fluid that is drawn into barrel 20. For example, FIG. 2 shows the location of abutment 360 for a 3 mL syringe; for a 5 mL syringe ledge 351A acts as abutment 360.

At the end of plunger 30 withdrawal, the fluid contents of syringe 10 are delivered by depression of plunger 30.

At the end of delivery, there are three events that occur.

Firstly, needle mount 40 is disengaged from barrel insert 50 to allow retraction of needle mount 40 and needle 12.

Secondly, plunger rod 31 engages needle mount 40 via engaging means 340 to retract needle mount 40 and needle 12.

Thirdly, plunger rod 31 and seal member 33 are disengaged to allow decompression of spring 70, which drives retraction of plunger rod 31, needle mount 40 and needle 12 coupled therewith.

At the end of delivery, in order to release needle mount 40 from barrel 20, plunger lip 366 of plunger 30 forcibly displaces respective arms 53A, 53B of barrel insert 50 radially outwardly in the direction shown in FIG. 3, to thereby disengage grips 56A, 56B from base rim 43 of needle mount 40. This is accompanied by barbs

342A, 342B of plunger rod 31 engaging ledges 47A, 47B in needle mount 40 to thereby facilitate retraction of needle mount 40 by plunger 30, as shown in FIG. 7A and FIG. 7B.

As can be seen in FIG. 8 and FIG. 9, plunger lip 366 of plunger 30 spreads arms 53A, 53B of barrel insert 50 radially outwardly as indicated by the solid arrows. Angled faces 57A, 57B of arms 53A, 53B slide against plunger lip 366, causing barrel insert 50 to slide towards O-ring 55 after grips 56A, 56B of arms 53A, 53B have cleared base rim 43 of needle mount 40. As best seen in FIG. 9, respective corners 58A, 58B of arms 53A, 53B come to rest on the outside of needle mount body 41 to permanently release the needle mount 40 and allow it to pass through barrel insert 50 and seal mount 33 which are retained at needle end 23 of barrel 20 by spring 70. At this location, barrel insert 50 can no longer retain a needle mount 40, thereby permanently disabling syringe 10 by preventing re-fitting of a needle mount 40.

As best seen in FIG. 7A, during engagement of respective plunger engaging means 44A, 44B in seal mount 40 by barbs 342A, 342B of plunger rod 31, inclined edges 343A, 343B of barbed arms 341A, 341B of plunger rod 31 bear against respective, complementary angled faces 46A, 46B on needle mount 40 which forces a slight rotation of plunger rod 31 relative to seal member 33 in the direction indicated by the arrow in FIG. 7A, which facilitates disengagement of bayonet coupling 300.

Disengagement of plunger rod 31 and seal mount 33 allows decompression of spring 70 which pushes against seal mount 33 and rim 330 on plunger rod 31 to

thereby force retraction of plunger rod 31 together with needle mount 40 and needle 12 engaged therewith. Seal mount 33 and barrel insert 50 remain at needle end 23 of barrel 20.

Disengagement of plunger rod 31 from seal mount 33 allows decompression of spring 70 and retraction of plunger rod 31 with needle mount 40 and needle 12 attached thereto, followed by activation of disabling means 80 to prevent subsequent movement of plunger rod 31. When plunger rod 31 rotates just prior to retraction, rib 63A of collar 60 slidably moves through gate 312 from slot 311 into retraction space 313, as shown in FIG. 6B, which thereby allows plunger rod 31 to retract while aligning pawls 62A, 62B of collar 60 with steps 350A, 350B of plunger rod 31.

Steps 350A, 350B are configured to allow travel of pawls 62A, 62B thereover as plunger rod 31 retracts, but to resist subsequent depression of plunger rod 31, by pawls 62A, 62B (not shown) bearing against steps 350A, 350B (not shown) once disabling means 80 has been activated, as shown in FIG. 10.

Also evident in FIG. 10 is that disabling means 80 prevents further withdrawal of plunger rod 31 by ribs 63A, 63B of collar 60 bearing against ledges 351A, 351B of plunger rod 31.

It should also be noted that following retraction of plunger rod 31 and needle mount 40, barrel insert 50, O-ring 55, seal mount 33 and seal 34 remain at needle end 23 of barrel 20 (not shown), thereby preventing refilling of barrel 20 from needle end 23.

It will be understood in light if the foregoing that the invention provides a robust, simple to operate automatically-disabling syringe that prevents subsequent

reuse and thereby minimizes the potential for disease transfer while also reducing the likelihood of needlestick injuries to the user.

Throughout the specification, the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Various changes and modifications may be made to the embodiments described and illustrated without departing from the present invention.

DATED this twenty-second day of October 2004

UNITRACT SYRINGE PTY LTD

by its Patent Attorneys

FISHER ADAMS KELLY

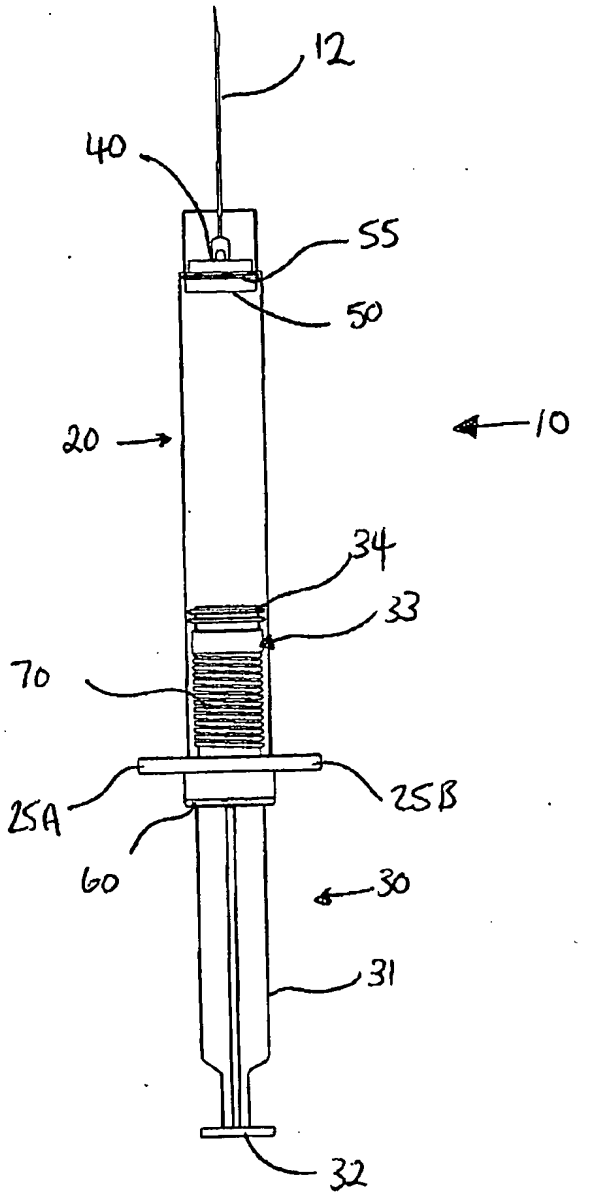
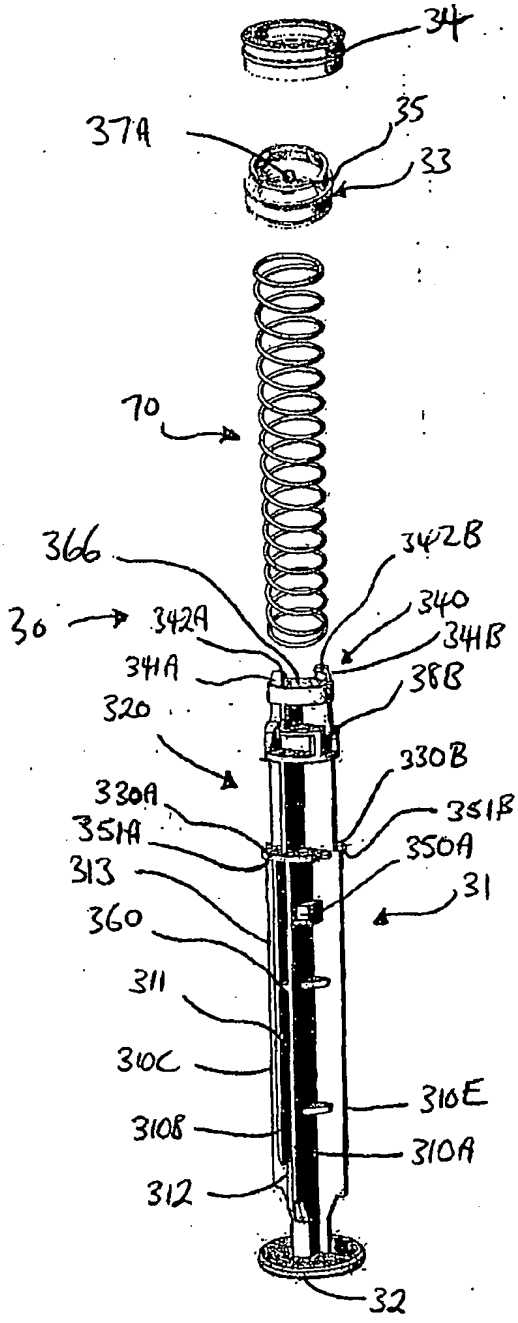


FIG. 1



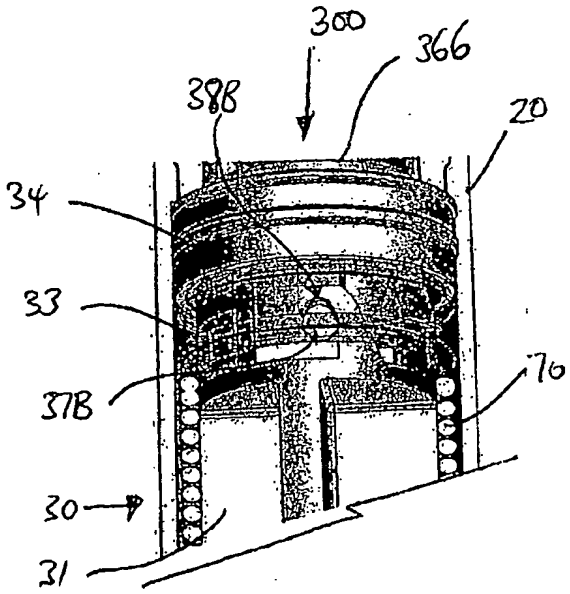


FIG. 2

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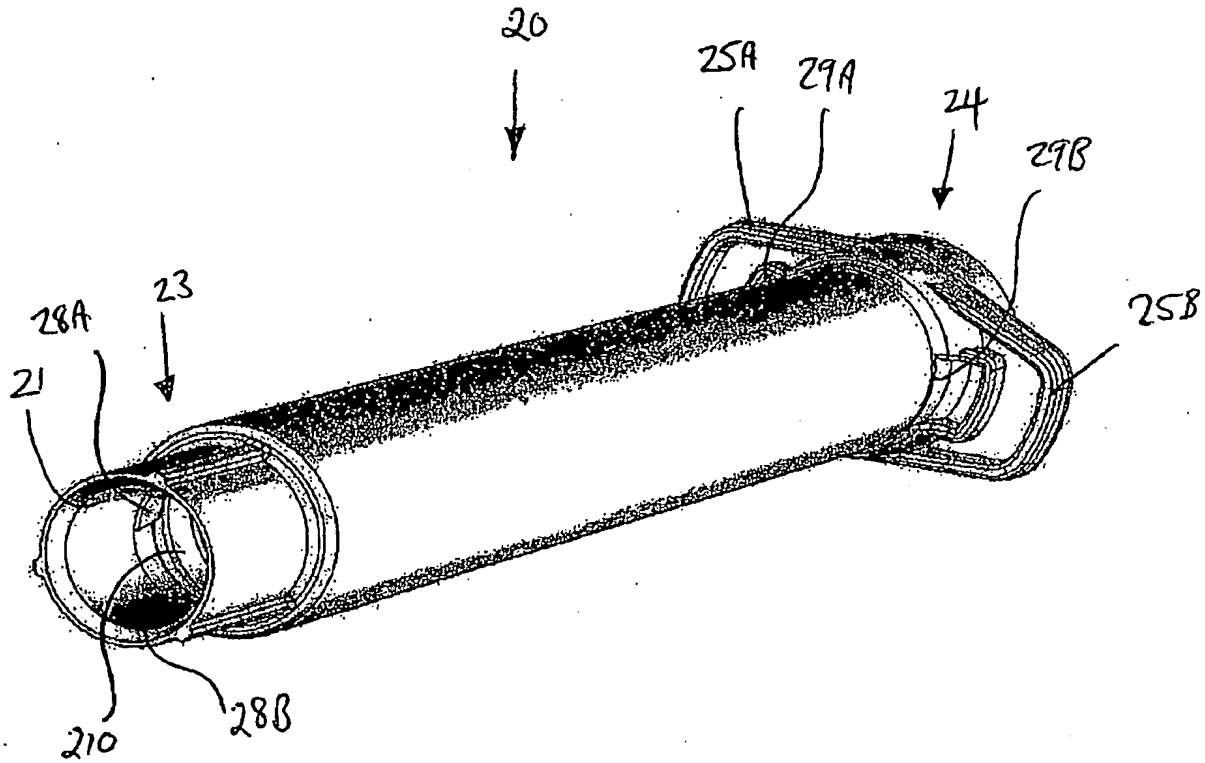

FIG. 3

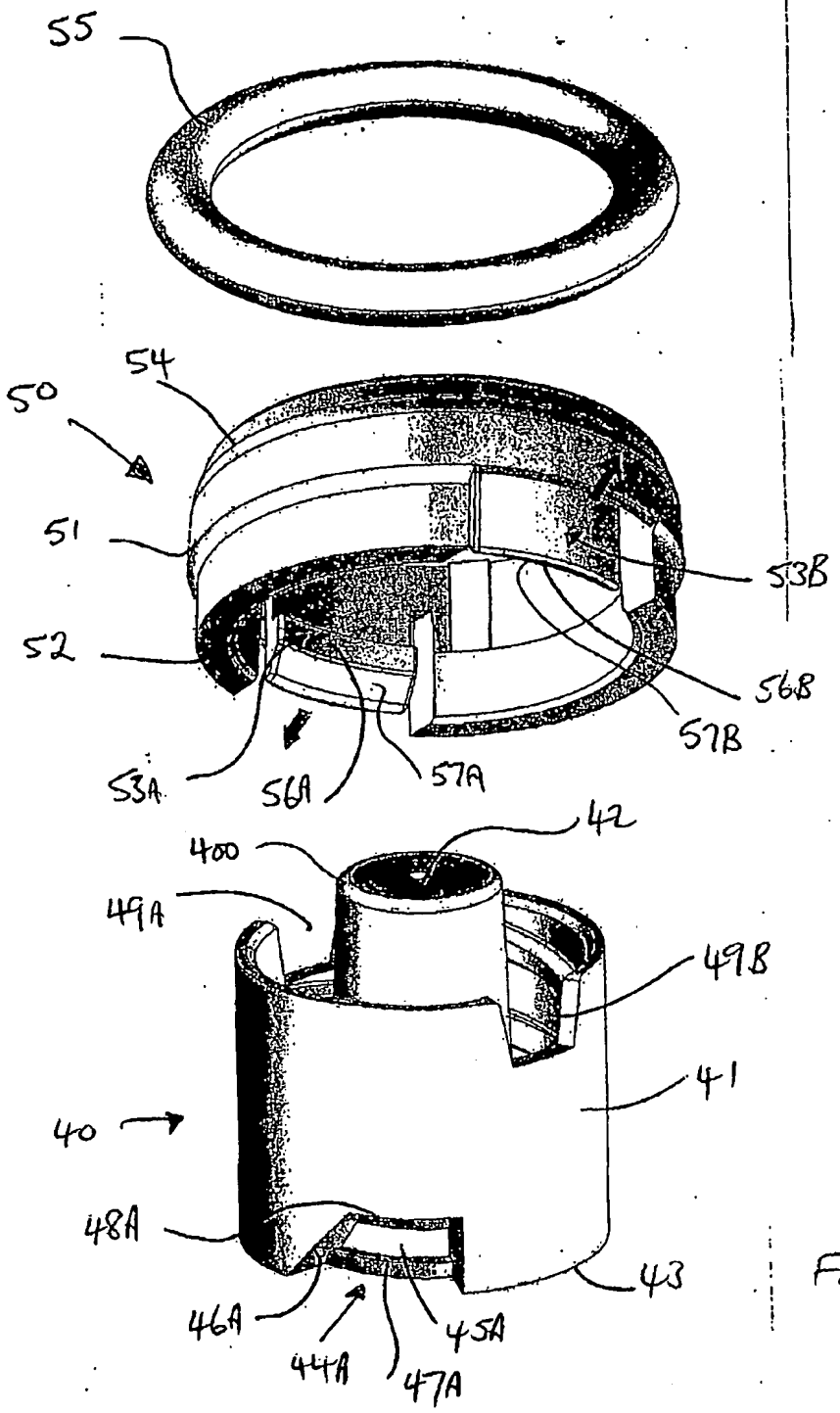

FIG. 4

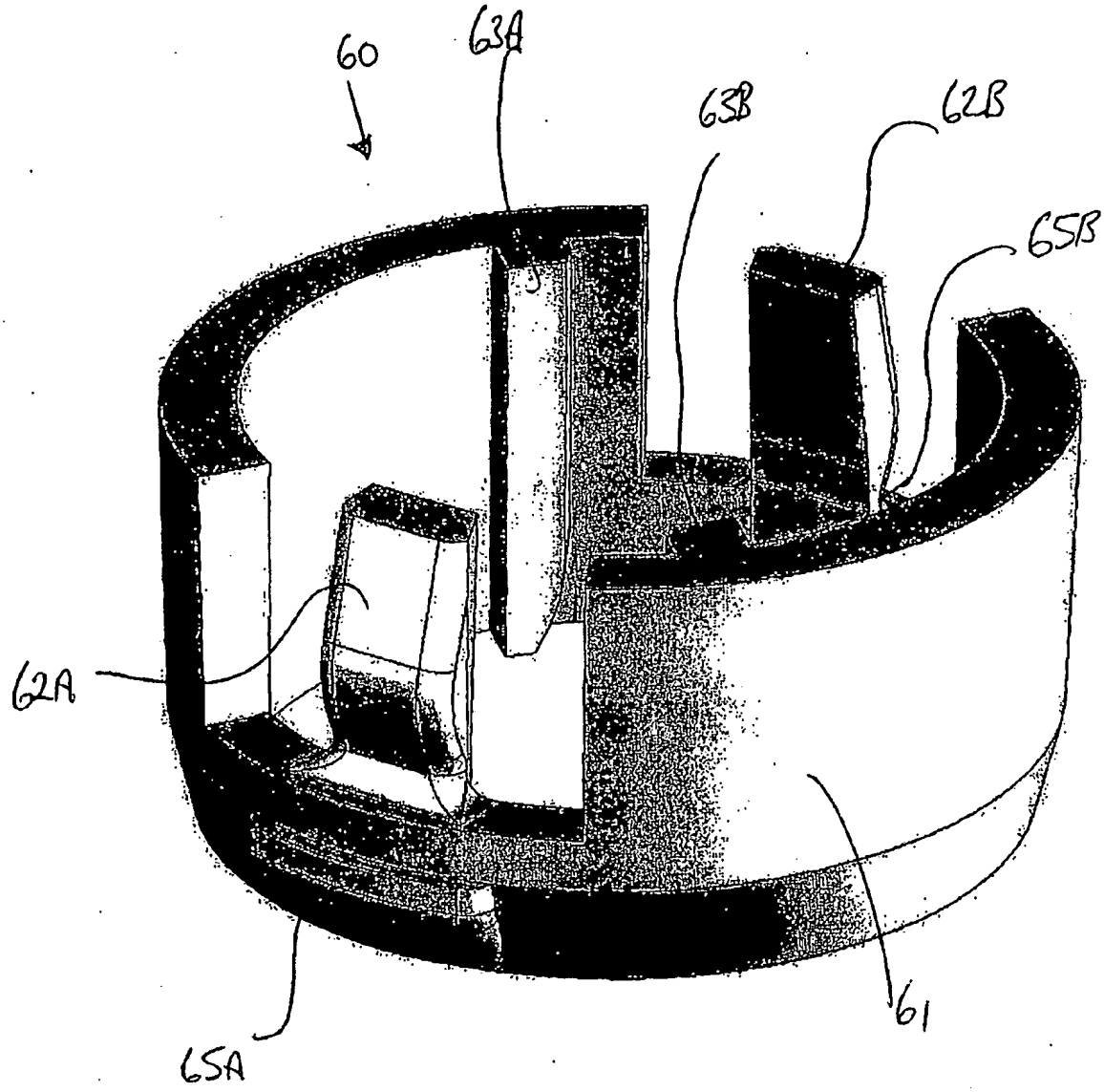

FIG. 5

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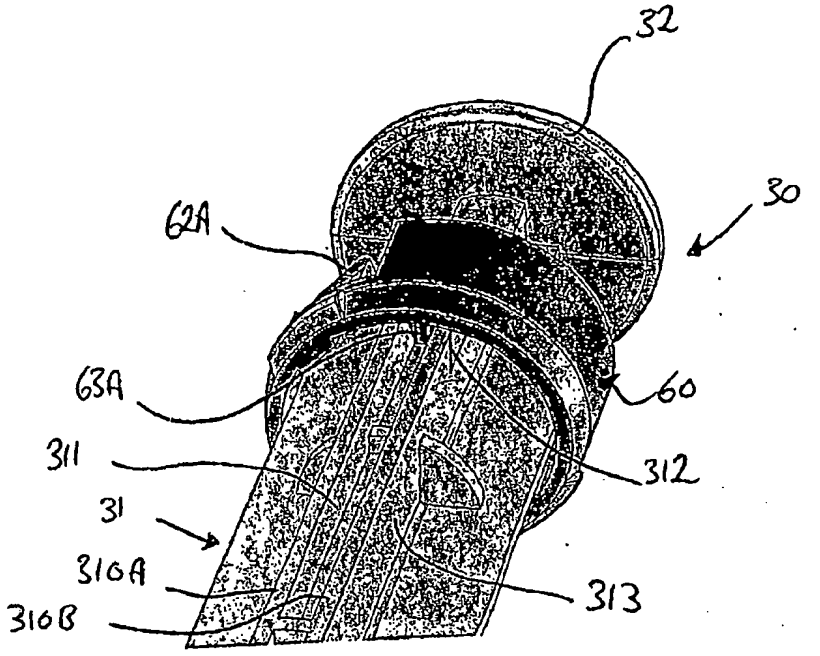

FIG 6A

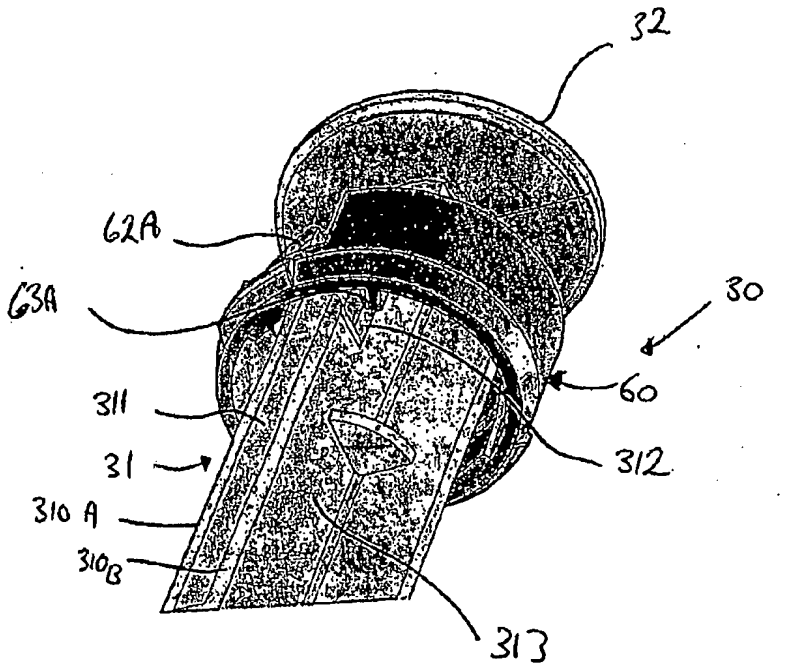

FIG 6B

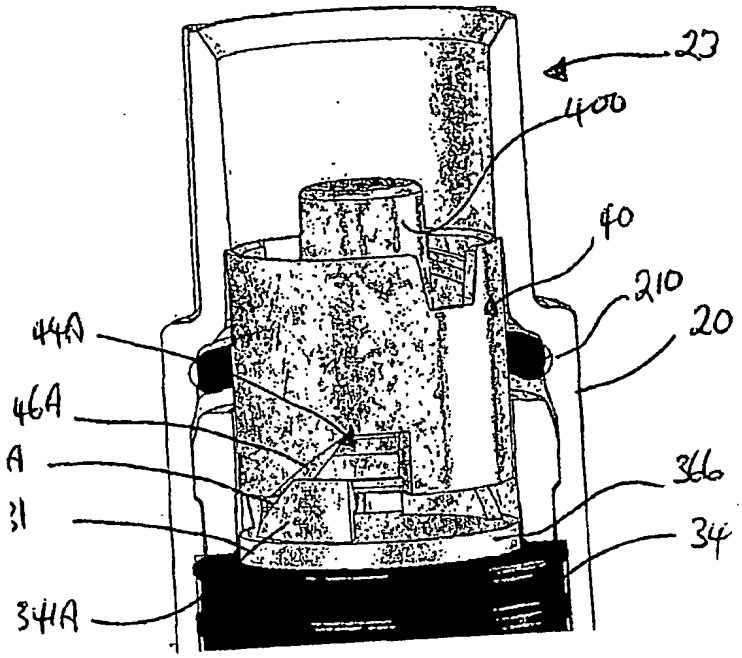
23
400
40
210
20
44A
46A
A
31
366
34
341A

FIG 7A

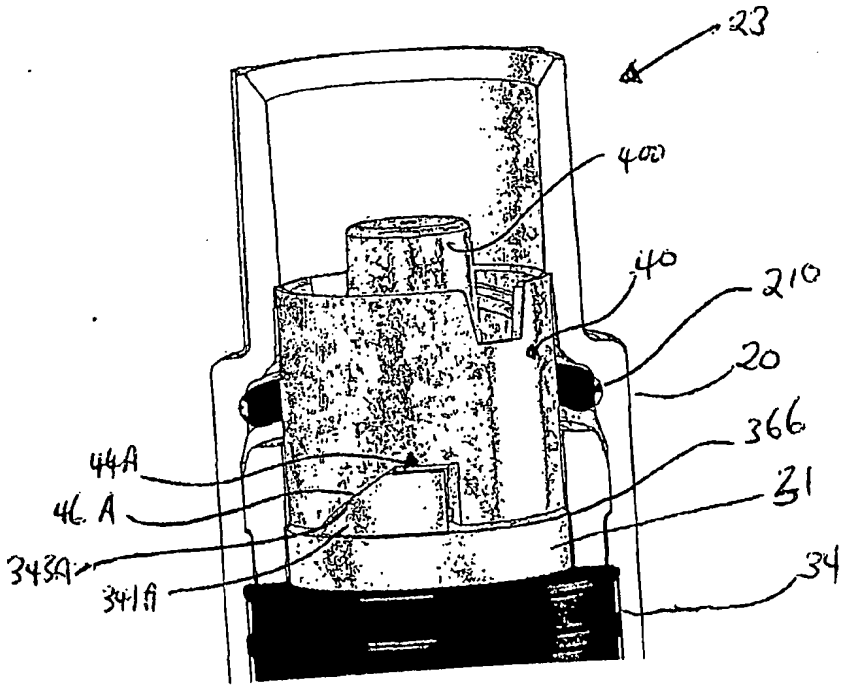
23
400
40
210
20
366
31
34
44A
46A
343A
341A

FIG 7B

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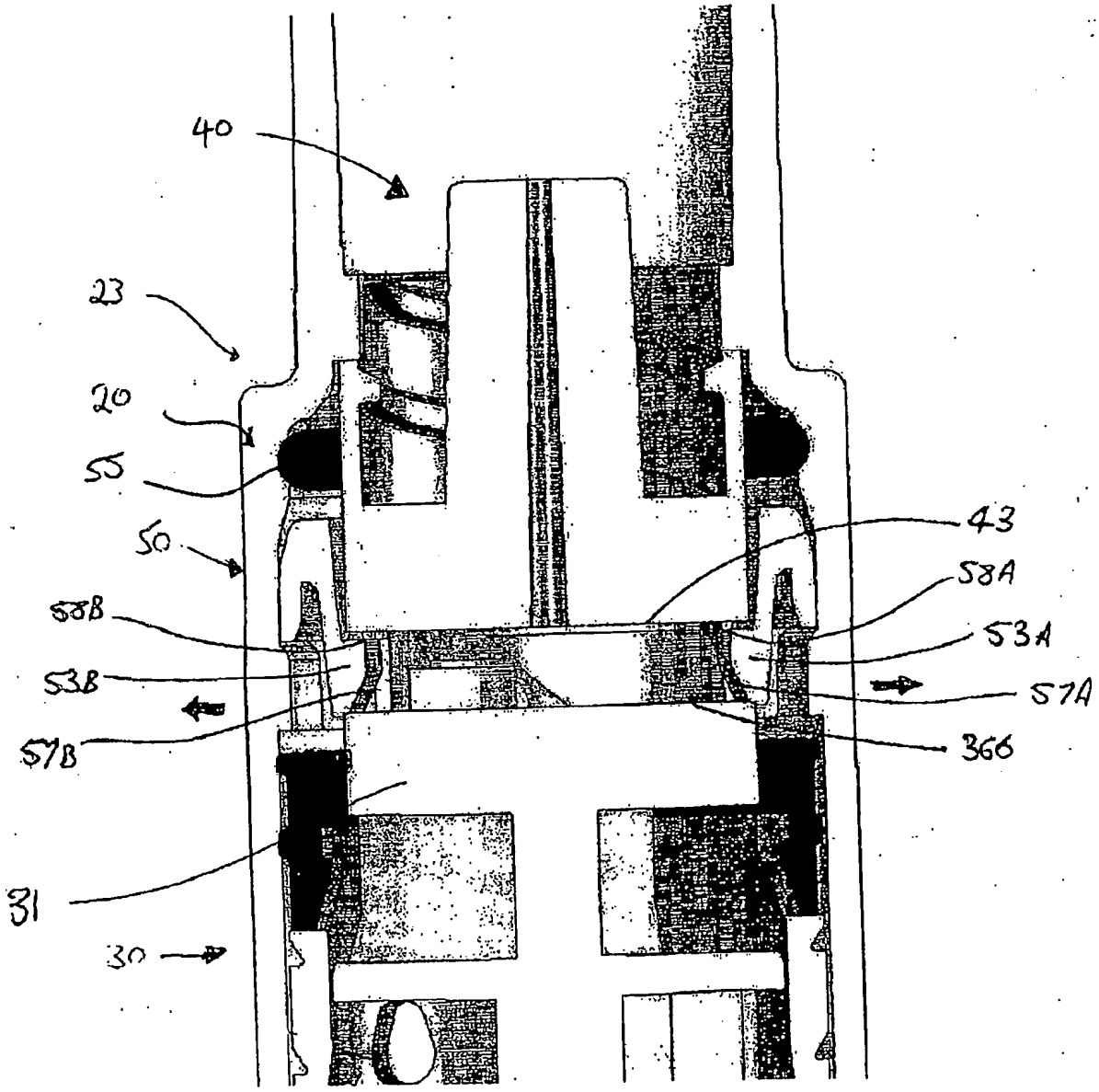

Fig. 8

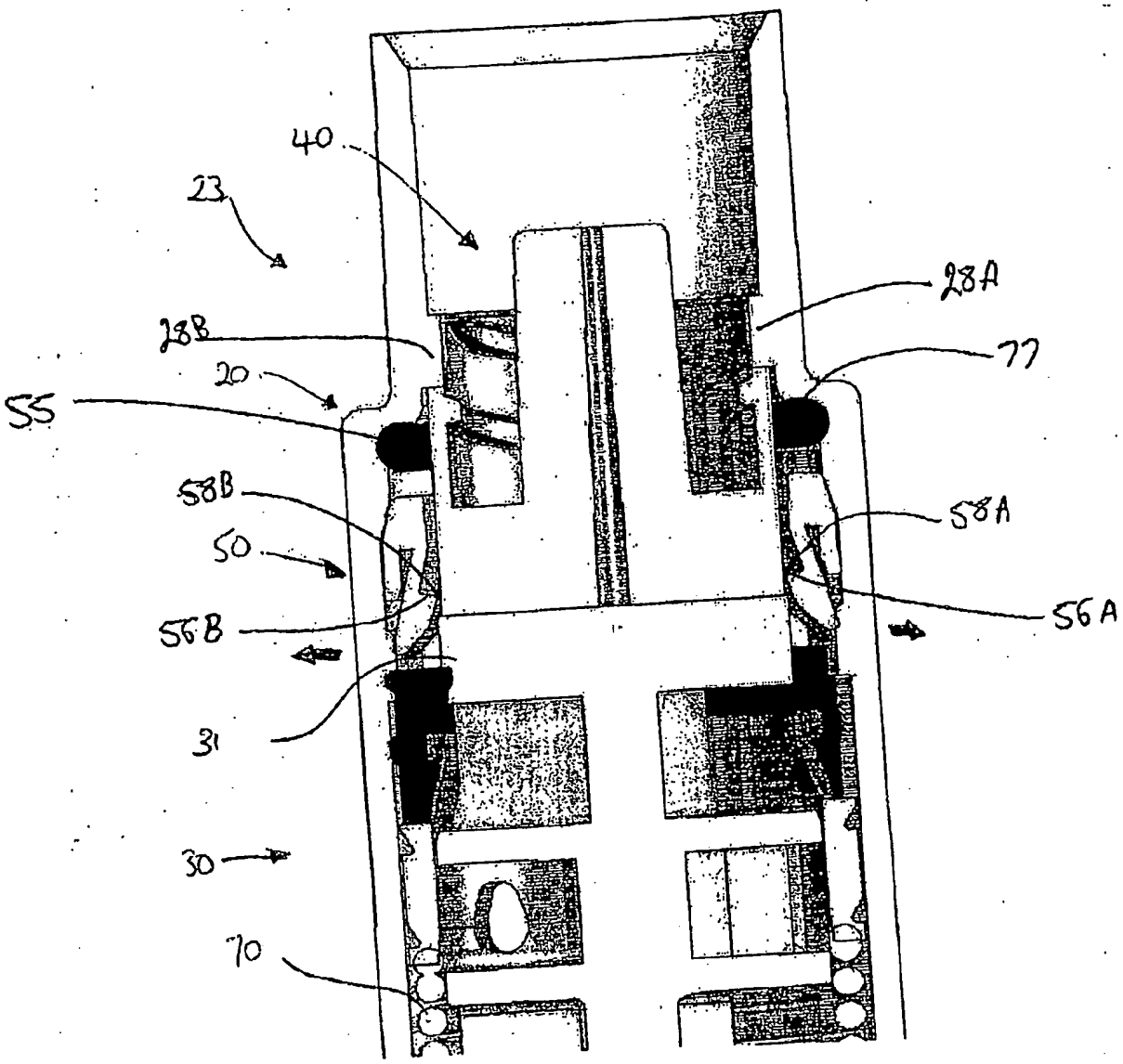

FIG. 9

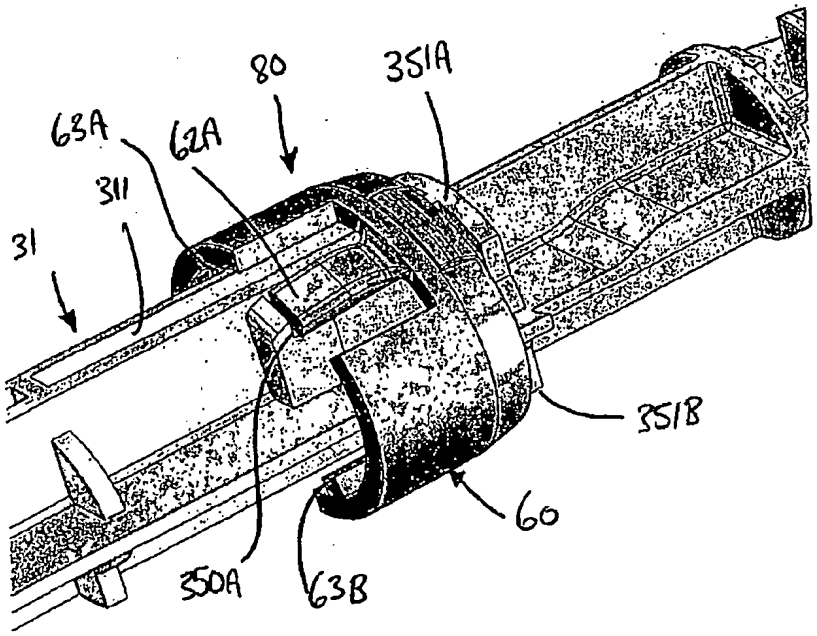

FIG. 10